510(k) Number: K031466
Device Name: IQmark Digital Holter

510(k) Summary

Submitter:

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Contact: Ruomei Zhang
Date of Summary: May 27, 2003

Name of Device:	IQmark Digital Holter
Common/Usual Name:	Holter Analyzer
Classification Name:	Electrocardiograph, ambulatory, with analysis algorithm (Per 21 CFR 870.2800)

Legally marketed devices to which Substantial Equivalence is claimed:
Rhythmscan Precision 6000 – 510(k) K914577, May 08, 1992
Syneview™ Holter ECG System (510(k) K990727, ELA Medical Inc.)

DESCRIPTION OF DEVICE:

The *IQmark Digital Holter* is a software program that analyzes recorded ambulatory ECG (Holter) then creates statistical reports based on analyzed data. The ambulatory ECG, as well as pacemaker pulse detection data, is pre-recorded onto data storage mediums by Holter recorders. The IQmark Digital Holter software reads these raw data into computers then performs analysis to generate statistical reports.

The IQmark Digital Holter software provides review and editing tools that allow trained medical personnel to review and edit the initial analysis results to diagnose patients. The IQmark Digital Holter software does not provide diagnostic interpretation.

The IQmark Digital Holter software also provides statistical results of pacing events for pacemaker patients. Like other features in the software, Holter scanning operators can review and edit, if necessary, any analysis results.

INTENDED USE OF DEVICE:

The intended use of the *IQmark Digital Holter* is for evaluation of the recorded ambulatory ECG for patients who need ambulatory monitoring, such as, but not limited to, those have complaints of chest pain, palpitations, dizziness, shortness of breath, or those have pacemaker implanted. The evaluation includes measurements and statistics of arrhythmia, R-R variability and ST segment changes in the recorded ECG data. The computer-generated results do not contain diagnostic interpretation, intended users are expected to review the report.

The *IQmark Digital Holter* is intended to be used only by physicians or on the order of a physician.

The intended use of the *IQmark Digital Holter* as described in its labeling has not changed from the cleared device, Rhythmscan Precision 6000 (K914577).

COMPARISON TO CLEARED DEVICES

The *IQmark Digital Holter* is originated from Rhythmscan Precision 6000 Holter software, with a new trade name and feature modifications. The modified Holter software has not changed the intended use of the device and has not changed the fundamental scientific technology of the device. Both devices have identical heartbeat categories: Ventricular Ectopics, Supraventricular Ectopics, Asystole (Pause) events and Normal heartbeats. Both devices generate statistical results based on an identical set of analysis results. Both devices do not generate diagnostic interpretation. Analysis results are expected to be reviewed by physicians. Physicians or scanning operators can use provided review and editing tools to verify ECG strips in all categories as well as their measurements and statistics.

Comparison Table between IQmark Digital Holter and predicate devices:

Holter Analyzer Devices	**IQmark Digital Holter**	**Rhythmscan Precision 6000**	**ELA Syneview Holter ECG System**
Company	Brentwood Medical Technology Corp.	Brentwood Medical Products	ELA Medical Inc.
510(k) Number	K031466	K914577	K990727
Raw Data Reader	Digital	Digital / Tape	Digital
ECG Channels	3	2 or 3	2 or 3
PC Based	Yes	Yes	Yes
PCMCIA Interface	Yes	Yes	Yes
Graphic User Interface (GUI)	Yes	Yes	Yes
Network Storage	Yes	Yes	Yes
Re-analysis	Yes	Yes	No

Arrhythmia Classification	Yes	Yes	Yes
Events Editing	Yes	Yes	Yes
ST Segment	Yes	Yes	Yes
Templates	Yes	Yes	Yes
Pacemaker Evaluation	Yes	No	Yes
Reports Editing	Yes	Yes	Yes
Reports Selection	Yes	Yes	Yes
Archiving	Yes	Yes	Yes
Printing ECG Strips	Yes	Yes	Yes
Printing Full Disclosure	Yes	Yes	Yes
Full Disclosure Storage	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Brentwood Medical Technology Corporation
c/o Ruomei Zhang, Ph.D.
Chief Technical Officer
3300 Fujita Street
Torrance, CA 90505

Re: K031466
Trade Name: IQmark Digital Holter
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II (two)
Product Code: MLO
Dated: May 27, 2003
Received: May 29, 2003

Dear Dr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031466

510(k) Number (if known): K031466

DEVICE NAME: IQmark Digital Holter

INDICATIONS FOR USE:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031466

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)